

[Counsel listed in signature block]

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

ILLUMINA, INC.,

Plaintiff/Counterclaim-
Defendant,

v.

NATERA, INC.,

Defendant/Counterclaim-
Plaintiff.

CASE NO. 3:18-CV-01662-SI

**JOINT CASE MANAGEMENT
CONFERENCE STATEMENT**

CMC Date: February 22, 2019
Time: 3:00 p.m.

JUDGE: HON. SUSAN ILLSTON

Pursuant to Northern District of California Civil Local Rule 16-10, plaintiff/counterclaim-defendant Illumina, Inc. (“Illumina”) and defendant/counterclaim-plaintiff Natera, Inc. (“Natera”) (collectively, the “Parties”) jointly submit this Case Management Conference Statement in advance of the Case Management Conference scheduled for **February 22, 2019 at 3:00 p.m.**, Courtroom 1, 17th Floor, 450 Golden Gate Avenue, San Francisco, California.

I. CASE STATUS

A. Brief Description of the Claims and Defenses Asserted in the Action:

U.S. Patent No. 9,493,831: Illumina brought this action against Natera, accusing Natera’s Panorama Prenatal Test of infringing U.S. Patent No. 9,493,831 (the “’831 Patent”), entitled “Methods of Fetal Abnormality Detection.” *See* Dkt. No. 1. Natera’s Panorama product is a prenatal test based on the use of cell free fetal DNA that tests for fetal genetic disorders. *See id.* Illumina contends that Natera’s infringement has been willful and seeks all available remedies, including damages and a permanent injunction. *See id.*

Natera denies that any of its accused products, including its Panorama prenatal test, infringe the asserted claims of Illumina’s ’831 Patent. *See* Dkt. No. 61. Natera has asserted counterclaims of non-infringement and invalidity, as well as affirmative defenses, including that the asserted claims are invalid and/or unenforceable for one or more reasons, including for failure to meet one or more of the requirements under 35 U.S.C. §101 *et seq.*, including but not limited to §§ 102, 103, and 112. *See id.* Natera contends that it has not willfully infringed, and does not willfully infringe, the asserted claims. *See id.* Natera also contends that Illumina’s claims are barred or limited under principles of equity. *See id.* Finally, Natera contends that Illumina is not entitled to any damages or injunctive relief. *See id.*

U.S. Patent No. 8,682,592: Natera filed a counterclaim against Illumina, accusing Illumina’s Verifi®, Verifi® Plus, VeriSeq™ PGS, VeriSeq™ NIPT of infringing U.S. Patent No. 8,682,592 (the “’592 Patent”), entitled “System and Method for Cleaning Noisy Genetic Data from Target Individuals Using Genetic Data from Genetically Related Individuals.” *See* Dkt. No. 61. Illumina’s Verifi® and VeriSeq™ products test for chromosomal abnormalities, such as aneuploidy, using

1 genetic material collected from a single cell or cells from an embryonic biopsy or cell free fetal DNA
 2 found in maternal blood. Natera asserts that Illumina's infringement has been willful and deliberate,
 3 and seeks all available remedies, including damages and a permanent injunction. *See id.*

4 Illumina denies that any of its accused products, including its Verifi® and VeriSeq™
 5 products, infringe the asserted claims of Natera's '592 Patent. *See* Dkt. 63. Illumina asserts that it
 6 has not infringed and is not infringing, directly, indirectly, contributorily, by inducement, or in any
 7 other manner, either literally or by the doctrine of equivalents. *See id.* Illumina has also asserted
 8 various defenses, including that the '592 patent is invalid for failure to satisfy the conditions of
 9 patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112. *See id.* Finally, Illumina asserts that
 10 Natera may not claim or recover any relief. *See id.*

11 **B. Key Events Since The Initial Case Management Conference:**

12 Key events since the initial case management conference are as follows:

- 13 • The Court denied without prejudice to renew on a fuller factual record,
 14 Natera's Motion to Dismiss Illumina's Complaint on the basis that the '831
 15 Patent comprises patent-ineligible subject matter (35 U.S.C. §101). *See* Dkt.
 No. 41.
- 16 • The Court also denied Natera's request to limit the proceedings to the question
 17 of whether the '831 Patent includes an inventive concept sufficient for patent
 18 eligibility under 35 U.S.C. § 101, holding that economies in discovery were
 speculative and an overlap in issues diminishes the possible benefits of
 bifurcation. *See* Dkt. No. 53.
- 19 • Natera filed a petition for *inter partes* review of the asserted claims of the '831
 20 Patent. *See Natera, Inc., v, Illumina, Inc.*, No. IPR2018-01317, Paper No. 1
 21 (P.T.A.B. June 29, 2018). On January 19, 2019, the Patent Trial and Appeal
 22 Board declined to institute *inter partes* review on the asserted claims of the
 '831 Patent. *See Natera, Inc, v, Illumina, Inc.*, No. IPR2018-01317, Paper No.
 15 (P.T.A.B. Jan. 19, 2019).
- 23 • The Parties submitted claim construction briefing requesting that the Court to
 24 construe one term in the '831 Patent and two terms in the '592 Patent. *See*
 25 Dkt. Nos. 69-76. On January 30, 2019, the Court issued its Claim
 Construction Order construing the three terms at issue. *See* Dkt. No. 81.

26 **C. Alternative Dispute Resolution:**

27 The Parties are open to exploring alternative dispute resolution, such as mediation, as a means
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1 to possibly resolving the Parties' disputes.

2 II. CASE MANAGEMENT ISSUES

3 1. Infringement of the '592 Patent

4 **Illumina's Position.** Illumina believes that in view of the Court's claim construction order
 5 any further allegations by Natera that Illumina's non-invasive prenatal testing ("NIPT") products
 6 infringe the '592 patent would be frivolous. In its claim construction order, the Court ruled that
 7 "both the claims and specification [of the '592 Patent] demonstrate that the claimed method is
 8 directed to the analysis of samples containing the DNA of only one individual." Dkt. No. 81 at 15.
 9 The accused Illumina NIPT products, however, analyze samples containing DNA not just from one
 10 individual, but the DNA of both the mother and fetus. Although Natera attempts to salvage its non-
 11 infringement case below, Natera is advancing a meritless theory relating to "individually measuring"
 12 that is simply wrong on the facts. In all of Illumina's NIPT products, fetal DNA and maternal DNA
 13 are measured *at the same time* on the Illumina flow cell. There is never any isolation of fetal DNA
 14 from maternal DNA and no distinction between fetal and maternal DNA. Accordingly, to the extent
 15 Natera continues to pursue infringement claims against the Illumina NIPT products, this case is
 16 plainly exceptional pursuant to 35 U.S.C. § 285.¹

17 **Natera's Position.** Natera disputes Illumina's assertion regarding the effect of the Court's
 18 claim construction order and notes that Illumina's current position conflicts with its argument during
 19 claim construction. Indeed, Illumina's position regarding the Court's construction is inconsistent
 20 with arguments Illumina advanced in support of its proposed construction, which the court adopted.
 21 For example, Illumina urged that it "is not arguing that the method cannot be applied to multiple
 22 individuals." Dkt. 74 at 16. Illumina framed its argument as "the claims require that, for each
 23 'individual' that is assessed, the claims are limited to measuring the data of that 'individual'
 24 separately from the data of any other individual." *Id.* As explained below, Illumina's accused
 25

26 ¹ Below, Natera further states that it "renews its request to focus the proceedings on the patent
 27 ineligibility of the subject matter claimed in the '831 Patent." Yet, Natera has not taken any
 28 discovery or identified any facts that would warrant this. If anything, the PTAB's denial of
 Natera's IPR request on the '831 Patent confirms that the claims of the '831 Patent include an
 inventive concept such that they are eligible under § 101.

1 products do just that—measure the DNA of the individual separately.

2 The Court construed “at least 100 loci on the chromosome or chromosome segment of interest
3 in the individual” to mean: “at least 100 loci on the chromosome or chromosome segment of interest
4 from only the individual.” Dkt. 81 at 15. Illumina’s accused NIPT products satisfy the claimed
5 limitation, as construed, because during sequencing, the DNA fragments are individually measured.
6 For example, during sequencing, only a single DNA fragment is able to bind to the DNA probes
7 within one nanowell of the flow cell such that only one DNA fragment is in one nanowell; that DNA
8 fragment is clonally amplified to form a cluster within that well. Each cluster is then sequenced on
9 Illumina’s sequencing instrument to generate “genetic data” on a given locus. Thus, DNA fragments
10 “from only the individual” (*i.e.*, the fetus) are clonally amplified and sequenced, separately from
11 other DNA fragments, to generate “genetic data for some or all possible alleles at a plurality of at
12 least 100 loci” on the chromosome of the individual. Indeed, Illumina literature indicates that in its
13 NIPT analysis, Illumina targets fetal cell-free DNA fragments:

14 Studies have shown that in a maternal sample, shorter cfDNA fragments tend to be
15 fetal in origin while longer fragments tend to be maternal (Figure 1). Using paired-
16 end sequencing, the VeriSeq NIPT solution can improve the signal-to-noise ratio by
17 selecting shorter fragments and make highly accurate calls using as little as one-
third the read depth of other sequencing assays. See <https://www.illumina.com/content/dam/illumina-marketing/documents/products/brochures/veriseq-nipt-solution-a4-brochure.pdf>. (last visited on February 19, 2019).

18 Even before the Court issued its claim construction order, Natera specifically sought discovery, by
19 way of interrogatories and requests for production, from Illumina regarding how it performs high-
20 throughput DNA sequencing to measure genetic material, including its “allele-specific
21 amplification” techniques. In response to Natera’s repeated demands that Illumina produce such
22 information, among other information, Illumina has delayed its production of such information.
23 Illumina’s efforts to avoid discovery in this case should not be rewarded.²

24 Moreover, Illumina does not dispute that, in addition to accusing Illumina’s NIPT products
25 of infringement, Natera also asserts that Illumina’s PGS (preimplantation genetic screening) tests
26

27 ² Natera intends to seek leave to amend its infringement contentions as to this claim construction
28 issue.

1 also infringe. To the extent Illumina argues that the Court's claim construction gives rise to non-
2 infringement arguments concerning its NIPT products, those arguments do not apply to Illumina's
3 PGS products. Thus, discovery will necessarily proceed regarding the technical details of Illumina's
4 PGS products, revenue associated with those products, and Illumina's contentions that the '592
5 Patent is invalid. It cannot, therefore, be said that bifurcating and focusing the proceedings with
6 respect to Illumina's NIPT products will lead to economy, nor will it lead to a ruling that would be
7 dispositive of all issues associated with the '592 Patent such that trial would not be necessary. *See*
8 Illumina's Opposition to Natera's Motion to Stay or, in the Alternative, to Limit Proceedings, Dkt.
9 No. 49 at 12-13.

10 Finally, to the extent the Court seeks ways to narrow the case, Natera renews its request to
11 focus the proceedings on the patent ineligibility of the subject matter claimed in the '831 Patent.
12 More specifically, the Court has already found "that the '831 is directed towards patent-ineligible
13 subject matter." Dkt. No. 41 at 6. The Court, however, found that "the factual record [was] not
14 sufficient for the Court to conclude whether there is an inventive concept." *Id.* at 7. Unlike
15 Illumina's request to expedite consideration of summary judgment regarding just a portion of the
16 Illumina products accused of infringing '592 Patent, a determination of ineligibility of the '831
17 Patent would have the effect of eliminating entirely further proceedings regarding that patent.
18 Additionally, now that claim construction has concluded, there is no longer a risk of duplicative
19 claim construction efforts. In fact, Natera believes that the positions Illumina took during the claim
20 construction, and the Court's claim construction ruling "that the '831 patent is directed toward
21 aneuploidy detection" (Dkt. No. 81 at 9) supports Natera's assertion that the claims of the '831 Patent
22 simply recite well-understood, routine, and conventional activities that are not sufficient to transform
23 the ineligible concept covered by the claims into patent-eligible subject matter.³

24 2. Case Schedule

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27 ³ Contrary to Illumina's assertion, patent eligibility under 35 U.S.C. § 101 was not at issue in the
28 IPR. Nor could it have been. 35 U.S.C. § 311 limits IPRs to "ground[s] that could be raised
under section 102 or 103 and only on the basis of prior art consisting of patents or printed
publications."

The Parties respectfully request that the Court enter the following schedule for completion of this matter:

Event/Local Rule	Proposed Date
Close of Fact Discovery	August 9, 2019
Opening expert reports for which party bears the burden	August 23, 2019
Rebuttal expert reports	September 20, 2019
Close of Expert Discovery	October 11, 2019
Deadline for Dispositive Motions	October 18, 2019
Dispositive Motion Opposition Briefs [Civil L.R. 7-3(a)]	November 1, 2019
Dispositive Motion Reply Briefs [Civil L.R. 7-3(a)]	November 8, 2019
Dispositive Motion Hearing [Civil L.R. 7-2]	November 22, 2019
Last day to file Joint Pretrial Conference Statement, trial witness list and summary of proposed testimony, deposition and written discovery designations, jury instructions, admissibility stipulations, motions in limine, and trial exhibits/objections [Judge Illston's Pretrial Instruction Nos. 1, 2, 3,	January 13, 2020

Event/Local Rule	Proposed Date
5(b), 6]	
Last day to file responses to motions in limine [Judge Illston's Pretrial Instruction No. 6]	January 27, 2020
Pretrial Conference	February 3, 2020
Trial (2 weeks)	February 10-21, 2020

1 Dated: February 19, 2019

Respectfully submitted,

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12 Dated: February 19, 2019

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CERTIFICATION

I, Derek C. Walter, am the ECF User whose identification and password are being used to file this Stipulation. In compliance with General Order 45.X.B, I hereby attest that Tracey B. Davies has concurred in this filing.

/s/ Derek C. Walter

Derek C. Walter